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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,749	12/22/2004	Takashi Nakayama	1422-0651PUS1	3018
2292 7590 07/22/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER				
SGAGLAS, MAGDALENE K				
ART UNIT		PAPER NUMBER		
1632				
NOTIFICATION DATE		DELIVERY MODE		
07/22/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/518,749

Applicant(s)

NAKAYAMA ET AL.

Examiner

Magdalene K. Sgagias

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Applicant's arguments filed 3/19/09 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-18 are pending and under consideration. Claim 19 has been canceled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 **remain** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record mailed 12/23/08.

A. Applicants respectfully submit that the previous claim amendment was the result of an inadvertent typographical error. However, the present claims have been properly amended in accordance with the present invention.

In response these arguments are not persuasive because the currently amended claim 1 is directed to identical previously presented subject matter but in a preferred writing style.

B. Applicants provide the following comments regarding the present claim amendment. Moreover, Applicants note that in the last Office Action, the Examiner did not acknowledge any of the scientific periodicals which were used to establish what those of ordinary skill at the time of the present invention would understand regarding the ability of the recited embryonic stem cells to differentiate into three primary germ layers and also germ cells. Applicants respectfully request that the Examiner consider the articles, which are again submitted for the Examiner's consideration, and provide comments regarding the articles, in the event that the Examiner does not find them to support the present claim amendment.

In response, these arguments are not persuasive because the disclosed IDS references by Thomson (PNAS, 92: 7844-7848, 1995) and Thomson (Science, 282: 1145-1147, 1998) do not overcome the issue of literal support for a method that encompass a method for producing isolated neural cells, wherein the method comprises carrying out a suspension culture of embryonic stem cells having the ability to differentiate into three primary germ layers and also germ cells, in the presence of an astrocyte conditioned medium or ingredients equivalent to the conditioned medium to directly produce said isolated neural cells.

Applicants argue that they acknowledge that literal support for the present claim amendment is not present in the specification. However, the subject matter of the claim need not be described literally (i.e., using the same terms or in haec verba) in order for the disclosure to satisfy the description requirement. Applicants argue the scientific periodicals at the time of the present invention also indicate that those of ordinary skill in the art would appreciate that the present inventors had possession of the presently claimed invention. Applicants submit herewith evidence (i.e., scientific periodicals) that those of ordinary skill in the art at the time of the present invention would understand that "embryonic stem cells" (as used by the inventors in this application) would "have the ability to differentiate into three primary germ layers and also germ

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cells". Applicants offer a brief statement of the relevance of each of the evidentiary documents below, for the Examiner's convenience. Thomson et al., "Isolation of primate embryonic stem cells", PNAS, Vol. 92, pp. 7844- 7848, (1995). This article relates to established embryonic stem cells of a monkey. In particular, at the left column on page 7844, it is disclosed that "Embryonic stem (ES) cells, derived from preimplantation embryos (1,2) and embryonic germ (EG) cells derived from fetal germ cells (3,4), are undifferentiated immortal cells capable of differentiating into derivatives of all three embryonic germ layers." Thomson et al., "Embryonic Stem Cell Lines Derived from Human Blastocysts", Science Vol. 282, pp. 1145-1147, (1998). This article relates to established human embryonic stem cells. The summary discloses that "Human blastocyst-derived, pluripotent cell lines are described that have normal karyotypes, express high levels of telomerase activity, and express cell surface markers that characterize primate embryonic stem cells but do not characterize other early lineages. After undifferentiated proliferation in vitro for 4 to 5 months, these cells still maintained the developmental potential to form trophoblast and derivatives of all three embryonic germ layers, including gut epithelium (endoderm), cartilage bone, smooth muscle and striated muscle (mesoderm); and neural epithelium, embryonic ganglia and stratified squamous epithelium (ectoderm)." Also, in the right column on page 1145, it is disclosed that "The human ES cell lines surface markers that characterize undifferentiated nonhuman primate ES and human EC cells, including stage-specific embryonic antigen (SSEA)-3, SSEA-4, TRA-1-60, TRA-1-81, and alkaline phosphatase." However, the Examiner should note that these markers are specific to human embryonic stem cells, so as not to be expressed in the cells disclosed in Weiss.

These arguments are not persuasive because both of the Thomson references do not support for producing isolated neural cells form derived from the same suspension of embryonic stem cells as claimed in the instant invention. As Applicants point out Thomson's neural

"Embryonic stem (ES) cells, derived from preimplantation embryos and embryonic germ (EG) cells derived from fetal germ cells and under distinct culture steps resulting into distinct culture method.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, Jr., can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Art Unit 1632

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
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